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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,202	06/24/2003	Andrew D. Firlik	33734-8046US	4373

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PERKINS COIE LLP  
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EXAMINER
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ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
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3762

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03/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/606,202	<b>Applicant(s)</b> FIRLIK ET AL.	
	<b>Examiner</b> ALYSSA M. ALTER	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-44 and 46-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-44 and 46-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed October 17, 2007 have been fully considered but they are not persuasive.

The Applicant argues that John teaches away from applying electrical stimulation at a level below a threshold of neurons at a stimulation sites. Furthermore, the Applicant states that John discloses and an adaptive brain stimulator that uses feedback in response to an electrically stimulated brain.

However, John does not solely use the feedback from the brain, but also utilizes EMG, blood pressure, tremor, etc. to determine the response to applied therapy. Therefore John does not teach away from sub threshold electrical stimulation.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear is one of the behavior therapy comprises several types of physical therapy or includes physical therapy. Furthermore, the claim appears to be an improper Markush group.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 30-44 and 46-51 are rejected under 35 U.S.C. 103(a) as obvious over John (US 6,066,163) in view of Collins (US 5,782,873). John disclosed an adaptive brain stimulation that aids in rehabilitation of patients suffering from traumatic brain injury, coma and other brain dysfunction.

As to claim 30, John discloses in col. 14, lines 43-50, "Sensory stimulation achieves excitation of such areas as the reticular formation, lemniscal pathways, specific and non-specific and cortical regions. Using the ABS, sensory stimulation parameters including intensity, duration, and frequency can be modified and the corresponding resultant present state compared to a reference state in order to choose the optimum stimulation parameters for creating cortical excitation".

As to claims 30 and 35, 37, 39-42, "the ABS system and method also contains devices for auditory stimulation such as headphones 56a, for visual stimulation such as LED goggles 56b, and for somatosensory stimulation such as a tactile stimulator 56c that is attached to the wrist or fingers of the subject, all of which are controlled and powered by the PC. These stimulation device enable the generation of auditory, visual, and somatosensory transient evoked potentials and steady state potentials that can be recorded from the EEG electrodes"(col. 5, lines 15-23).

The therapy that includes the use of LED goggles for visual stimulation elicits a visual stimulus, and thus is a visual task. Visual stimulus is also a reading task and attention task. Also, tactile stimulation would naturally be “volitional use of an affected body part” as claimed by the Applicant, as well as part of the “activities of daily living” and physical therapy. In addition, the behavior therapy occurs simultaneously with electrical or cortical stimulation therapy.

John discloses the device substantially as claimed but fails to teach delivery of stimulation below a threshold level for neurons at the stimulation site. Collins teaches that it is known to input sub-threshold stimulus to the sensory cell area for the purpose of effectively lowering the threshold of the sensory cells for enhancement in healthy individuals and treatment for those whose sensory system is degraded by disease, such as peripheral neuropathies or strokes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stimulation signal as taught by John with the sub-threshold stimulation signal as taught by Collins, in order to provide the predictable results of effectively lower the threshold of the sensory cells to facilitate enhancement therapy to the sensory cells.

As to the claims, such as claim 38, “in addition to the previously described types of direct electrical brain stimulation, stimulation of all five senses, both separately and in combination, has been shown to be effective in decreasing the time spent in coma (Sosnowski C, et al. Early intervention: coma stimulation in the intensive care unit. J Neurosci Nurs. 1994 December; 26(6): 336-341; Mitchell S, et al. Coma arousal procedure: a therapeutic intervention in the treatment of head injury. Brain Inj. 1990

July; 4(3): 273-279. Wood R L, et al. Evaluating sensory regulation as a method to improve awareness in patients with altered states of consciousness: a pilot study. Brain Inj. 1992 September; 6(5): 411-418.)" (col. 14, lines 32-43). Therefore, sensory stimulation affects awareness and thus provides cognitive therapy.

As to 30 and 36, "a present state of a patient can be divided into a "stimulation period" and a "post-stimulus period." The stimulation period is defined as a period that is in, or is temporally close to, the period in which stimulation occurs, for example from stimulation onset until stimulation offset or lasting up to, for example, 1 second post-stimulus 62c. The stimulation period may also be sub-divided into two or more smaller sections of interest 62a, 62b. The "post-stimulus period" may similarly be a single period or may be divided into two or more sub-periods 62c, 62d, 62e which begin after the stimulation period and last until the next stimulation period. The post-stimulus period may be characterized by complete cessation of stimulation or by a relatively decreased level of stimulation compared to the stimulator state." (col. 6, lines 54-67). John describes the post-stimulus lasting until the next stimulation period, which is indicative "of a therapy period that includes at least one session", as claimed by Applicant.

As to claims 31-32, "After the patient regains consciousness by returning from the coma or manifest an other desired improvement by recovering from a dysfunctional state, the ABS system can be implanted into a patient and aid in the subsequent maintenance of the normal state"(col. 3, lines 63-67). Thus, stimulation is ceased when a "predetermined level of functional recovery" is achieved, as claimed by Applicant.

As to claims 33-34, the direct brain stimulator (DBS) 50 is depicted in figure 1.  
“DBS's can consist of implanted electrodes or stimulating devices” (col. 12, lines 55-56).

***Specification***

1. The specification stands objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).  
Correction of the following is required: Claims 35 and 40 recite the limitation "volitional" in line 4 and line 2, respectful. The specification does not provide antecedent basis for the limitation “volitional use”.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Alyssa M Alter/  
Examiner  
Art Unit 3762